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| 10/567,700 | 02/03/2006 | Kyogo Ito | 3190-090 | 4014 |

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| EXAMINER | |
|---|---|
| HUFF, SHEELA JITENDRA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1643 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/567,700 | ITO, KYOGO | |
| | Examiner | Art Unit | |
| | Sheela J. Huff | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 03 February 2006 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 7/3/6,5/4/6,4/10/6.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-19 are pending.

### *Information Disclosure Statement*

The IDS filed 7/3/06, 5/4/06 and 4/10/06 have been considered and initialed copies of the PTO-1449 are enclosed.

### *Oath/Declaration*

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The full name of each inventor (family name and at least one given name together with any initial) has not been set forth.

Specifically, the last name of the inventor is misspelled. The declaration says ITO whereas the corresponding WO document (WO 2005/011723) states ITOH.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. claim 12 does not recite what the method will be performed in--thereby rendering the claim vague and indefinite.

b. In the claims, it is not clear if the agent is the peptide or if applicant is trying to claims these 'agent" claims as composition claims. If they are composition claims then the claims need to recite a second component.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to peptides having an amino acid sequence selected from the group consisting of SEQ ID NO. 1-10. While the amino acid sequences of SEQ ID NO:1-10 are adequately described in the specification as-filed, thereby providing an adequate basis for the peptide of SEQ ID NO:1-10; there is insufficient written description as to the identity of a peptide having an amino acid sequence selected from the group consisting of SEQ ID NO. 1-10 that would still maintain the function of the polypeptide. Consequently, the specification does not provide an adequate written description of peptides having an amino acid sequence selected from the group consisting of SEQ ID NO. 1-10

The specification as filed does not provide adequate written description support for peptide having an amino acid sequence selected from the group consisting of SEQ ID NO. 1-10. Peptides having diverse functions are encompassed by said phrase. Thus a broad genus having potentially highly diverse functions are encompassed by said phrase and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. The claims encompass peptides comprising SEQ ID NO. 1-10 thus, for example, SEQ ID NO. 1 can have any number of unspecified amino acids on either side of it. Applicant has not provided sufficient written description of what is on either side of SEQ ID NO. 1.

Therefore, only SEQ ID No. 1-10 meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for generating an immune response in vivo using SEQ ID NO. 1-10, does not reasonably provide enablement for a method for preventing

and/or treating hematologic malignancies in vivo using SEQ ID NO. 1-10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims and discloses agents that can prevent and/or treat hematologic malignancies (such as leukemias, lymphomas and myelomas, see page 16 of the specification) using SEQ ID No. 1-10. The data provided in the specification is in vivo data in humans which shows that an immune response can be generated in response to the above peptides. However, Haigh et al Oncology vol. 13 p. 1561-1574 (1999) clearly shows that "the induction of immune responses does not necessarily confer a therapeutic benefit" (abstract). Furthermore, Pinilla-Ibarz et al Blood vol 95 p. 1781 (2000) states that even though peptide based vaccines have undergone phase I trials, it is not clear what the efficacy of these peptides vaccines will be (see last page-last paragraph). Essell (J. NIH Res. 1995 7:46) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly the last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p. 48, para 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think

about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work". As a venture capitalist of the director of product development at a large pharmaceutical company and you're likely to get the same response." (p. 1 para 1).

Furthermore, Boon (Adv. Can. Res. 1992 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerate or at least depress the capability to respond against the tumor (p. 206, para 2).

Thus, in view of the contemporary knowledge in the art which shows that the generating an immune response does not translate to a therapeutic effect and in view of the unpredictability of the cancer vaccine art it is the Examiner's position that one of skill in the art would be forced into undue experimentation in order to use the invention as claimed.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 7-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/062257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of the claims is the scope of the peptides. The claims in each claim set have SEQ ID NO. 1-3 in common and each claim set also includes other peptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 6-11, 14-15 and 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 5, and 11 of copending Application No. 10/781659. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the two sets of the claims is the scope of the peptides. Peptides of SEQ ID NO. 8 and 9 of the instant application are SEQ ID NO. 3 and 6, respectively of the 659 application. The only difference between the two sets of claims is that each set of claims also includes other peptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-3, 6-11, 14-15 and 17-19 are directed to an invention not patentably distinct from claims 2-3, 5 and 11 of commonly assigned 10/781659. Specifically, the reasons for not being patentably distinct have been discussed above..

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/781659, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-11 and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1074267.

This reference discloses SEQ ID NO. 26, 4, 18 and 21 which are SEQ ID NO. 10, 4, 8 and 9 respectively of the instant invention. The reference also discloses the use of

the peptides as vaccines and using an adjuvant (p. 8, lines 1-5 and 56+). The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-2, 6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang US 2003/0077289.

This reference discloses the sequences VYDYNCHVDL and AYIDFEMKI (see Table 3) which are SEQ ID NO. 8 and 9 respectively of the instant invention. The terminology "for preventing and/or treating hematologic malignancies" and "vaccines" are intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-5, 7-11, 13-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh US 2002/0128201.

This reference discloses SEQ ID NO. 1-3 which are SEQ ID NO. 3, 2, 1 respectively of the instant invention. The reference also discloses the use of the peptides in pharmaceutical compositions and using an adjuvant (section [0113]). The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-3, 6 and 8-10 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Database Genseq, Accession Numbers AAY51121, AAY51122 or AAY51129.

These accession numbers disclose sequences which are SEQ ID NO. 5-7 respectively of the instant invention. The reference also discloses the use of the peptides in treatments and diagnostics and this inherently means that the peptides are used in pharmaceutical compositions. The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-3, 6 and 8-10 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Database Genseq, Accession Numbers AAG68080, AAG68079, AAG68085, AAG68086 or AAG68087.

These accession numbers disclose sequences which are SEQ ID NO. 2-4 and 8-9 respectively of the instant invention. The reference also discloses the use of the peptides in treatments and this inherently means that the peptides are used in pharmaceutical compositions. The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-2, 4-11, 13 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh US 6555652.

This reference discloses SEQ ID NO. 3 which is SEQ ID NO. 4 of the instant invention. The reference also discloses the use of the peptide in compositions and using an adjuvant (column 9 lines 20+). The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-2, 5, 7-11, 13, 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Itoh US 7071294 (filed 6/1/01).

This reference discloses SEQ ID NO. 4 and 9 which is SEQ ID NO. 10 and SEQ Id NO. 10 with extra amino acids respectively of the instant invention. The reference also discloses the use of the peptides in pharmaceutical compositions and using an adjuvant (col. 4, lines 53+ and col. 9, lines 29+). The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-3, 6-11, 14-15 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Itoh US 2006/0140968 (filed 2/28/01).

This reference discloses SEQ ID NO. 3 and 6 which are SEQ ID NO. 8 and 9 respectively of the instant invention. The reference also discloses the use of the peptides in pharmaceutical compositions and using an adjuvant (section [0066]). The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

Claims 1-3, 6, 8-10 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Savage US 2004/0096429 (filed 12/3/02).

This reference discloses peptides VYDYNCHVDL, AYIDFEMKI, DYSARWNEI, AYDFLYNYL AND SYTRLFLIL (see page 8, tables 3 and 4) which are SEQ ID NO. 5-9 respectively of the instant invention. The terminology "for preventing and/or treating hematologic malignancies" is intended use and carries no patentable weight when evaluating compound/composition claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sheela J Huff
Primary Examiner
Art Unit 1643

sjh